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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,794	10/15/2003	Kent Jardemark	58073 (47137)	9727
21874 7590 08/13/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
KOSSON, ROSANNE				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
08/13/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,794

Applicant(s)

JARDEMARK ET AL.

Examiner

Rosanne Kosson

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-54, 66, 68-70, 72-74 and 92-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-65, 67, 71 and 75-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/14/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicants' elections without traverse of the species of hydrophilic material (claim 62) and scanning the cell relative to the microchannel outlet (claim 76) in the reply filed on July 7, 2008 are acknowledged. As previously discussed, if certain generic claims are found to be allowable, the corresponding species will be rejoined. No claims have been amended, canceled or added. Accordingly, claims 55-62, 64-65, 67, 71 and 75, 76 and 79-91 to the extent that they read on the elected invention are examined on the merits herewith.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-62, 64-65, 67, 71 and 75, 76 and 79-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 55 and 60 in particular are confusing and ambiguous in their recitation of the claimed microfluidics system, so that the structure of the claimed apparatus cannot be understood, rendering the meaning of claims unclear. Claim 55 recites a solid, planar substrate and material having at least one raised aperture with a tip and comprising a measurement chamber with a microchannel. But, the substrate and the material appear to be the same component, and it is not clear what the difference is. It is not clear if the substrate/material is a one-piece device (a molded plate having an internal or external plumbing system and wells or reservoirs) or a two-piece device (with the apertures and tips in the upper part and the plumbing and wells in the lower part).

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Also, it is not clear what the measurement chamber is. Additionally, the microchannel need not be connected to anything but the measuring chamber, and the measuring chamber need not be connected to anything. Thus, the structure and how the claimed apparatus is used are unclear. Claim 60 recites the same apparatus as claim 55 with the change that the apertures are solid electrode tips. Clarification and appropriate correction are required.

Claim 90 is confusing, because the phrase "scanning a cell across the aqueous streams from the microchannels" is unclear. It cannot be determined where the cell is in the claimed microfluidics system, relative to the microchannels or the measurement chamber or the planar substrate/material. Appropriate correction reciting a clear and definite structure is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55, 57-59, 67 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Doellgast (US 5,078,164). Doellgast discloses a microfluidics system comprising a microtiter plate attached to (clamped to) a microtiter plate washer for automated dispensing and washing of the contents in the wells of the microtiter plate for high-throughput experiments (see col. 1, lines 10-59). The microtiter plate and washer lid are a substrate and substantially planar solid material. The microtiter plate comprises circular measurement chambers. The lid comprises an array of raised apertures with tips, internal to which is an array of microchannels that open into the measurement chambers. The plumbing in the lid can be connected to fluid reservoirs (see Figs. 2, 3A, 3B, 4 and 9-11; col. 2, lines 11-34; and col. 9, lines 19-42). Fluids (liquids and

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gases) are added to the wells under controlled pressure (see col. 3, lines 16-21). Because the apparatus is designed to conduct biochemical experiments such as immunoassays, the liquid reagents used with the apparatus are those compatible with cells and proteins. Thus, these liquids (which are conducting media) contain buffers and physiological salt solutions, which are electrolytes.

In view of the foregoing, a holding of anticipation is required.

Claims 60, 61, 62, 64, 65, 67, 75, 76, 79-83, 86-88 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Peeters (US 6,123,819). Peeters discloses a nanoelectrode array comprising a planar solid material that is included in a measuring chamber that can retain fluids. The array and the chamber are connected to a microfluidics system for the delivery and removal of materials to and from the array via microchannels. The array is connected to a microcontroller or microprocessor, which analyzes signals from the microelectrodes and controls the microfluidics system. The pressure in the microchannels is controlled by an external micro-pump (see Figs. 1-3 and 5; col. 3, lines 21-35; and col. 8, line 38, to col. 9, line 7). The nanoelectrodes are exposed to a micro-channel, or to a network of micro-channels, which deliver a mixture of biological molecules (proteins) to the nanoelectrodes for separation and analysis (see col. 7, lines 7-21). Solutions of biomolecules may be delivered via multiple separate microchannels into a measurement chamber (see Fig. 5). The nanoelectrodes are tapered for insertion into cell structures, proteins or complex molecules (see Figs. 1-3). A suspension of cells may be delivered to a chamber anterior to the one containing the array, where the cells are lysed and their contents are analyzed on the array (see col. 6, lines 18-21). Because the solutions used are compatible with cells and proteins, liquid conducting media containing electrolytes are used.

The nanoelectrodes have a diameter of less than one micron (see col. 5, lines 6-26) and a contacting surface made of a hydrophilic material, a metal or a thiol-coated metal (see col. 5, lines 6-26).

Scanning of the nanoelectrode array in the x-y plane at specific positions is computer-controlled and very precise, similar to scanning a DNA chip, and scanning may be performed with a laser. Thus, the laser can scan a cell structure such as protein on the array relative to a microchannel outlet when the chip array of Figs. 1-3 is used in one of the chambers in Fig. 5. Signals from the electrodes can be amplified via transistors. See col. 10, lines 20-30; and col. 10, line 41, to col. 11, line 6) (see claims 76, 79-83, 86, 87, 90, 91.

In view of the foregoing, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 55-62, 64-65, 67, 71 and 75, 76 and 79-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters (US 6,123,819) in view of Chow et al. (US 5,800,690). The teachings of Peeters are discussed above.

Regarding claim 56, this claim corresponds to the device of Peeters in which one of the measurement chambers in Fig. 5 is round instead of square or rectangular from a bird's eye view. The specification does not disclose that the shape of the chamber is associated with any particular advantageous effect or result that is not disclosed by the prior art. Therefore, the choice of round vs. square appears to be an experimental design choice. One of ordinary skill in the art at the time of the invention would have been able to manufacture a microfluidics chip with wells or chambers of any conventional geometric shape. Therefore, this claim does not distinguish the claimed invention over the prior art. Chow et al. disclose a covered microfluidics chip/device having an array of nanoelectrodes in the wells of the device, and the wells are round (see Figs. 1 and 4 and cols. 1, 2 and 4). Thus, round chambers connected to microchannels are not novel to Applicants.

Regarding claims 84-85, Peeters does not disclose that the operation of the scanning mechanism (e.g., the rate, direction or number of repetitions of scanning) is responsive to a signal from the detector. But, it would have been obvious to one of ordinary skill in the art at the time of the invention that, if the nanoelectrode array, following an experiment, showed regions of interest (e.g., particularly high or low amounts of bound molecules or cell fragments), the software controlling the scanner would have been manipulated to scan in greater detail those regions of interest. Those regions of interest would have been scanned at a different speed to obtain better resolution, and multiple scans would have been performed. Therefore, these claims do not distinguish the claimed invention over the prior art.

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Regarding claim 89, it would have been obvious to one of ordinary skill in the art at the time of the invention to configure the plumbing in the microfluidics chip/device to include as many channels and inlet valves as were required to supply all the needed reagents to the nanoelectrode array. The design of the plumbing would have been well within the capability of the artisan of ordinary skill. Therefore, this claim does not distinguish the claimed invention over the prior art.

Regarding claim 90, as discussed above, it cannot be determined from the claim language where the cell is located relative to the microfluidics chip/device. But, the laser scanner and the imaging equipment would have been readily programmed by one of ordinary skill in the art at the time of the invention to detect one or more cells at any desired location within a measurement chamber containing the microfluidics chip/device. Therefore, this claim does not distinguish the claimed invention over the prior art.

In view of the foregoing, a holding of obviousness is required.

No claim is allowed.

Art of Record

Maher et al. (US 2002/0025568 A1) disclose an array of microelectrodes for use in a microtiter plate. The electrodes may be solid or fluid filled (patch clamp electrodes). See Figs. 1, 3 and 9 and paragraphs 11, 15, 136, 137, 143, 144, 160, 197, 198, 202 and 205-208.

Colbert et al. (US 2002/0084410 A1) disclose a nanoelectrode array of carbon fiber electrodes that may be modified in shape and by chemical derivitization of the surface with a wide variety of functional groups (see Figs. 1A-1E, 8, 12 and 13 and paragraphs 7, 8, 11, 14, 34, 40-44, 81, 89 and 130-132).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652
rk/2008-06-04

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657